DISCUSSION:

Examiner is thanked for a careful and clear analysis.

Claim 13 was rejected under Sect. 112. Claim 13 is amended to place it in the form that was stated to be allowable in the previous office action, by incorporation of claim 1 as originally submitted. The rejection is believed to be inapplicable to claim 13 as amended, and amended claim 13 is believed to be allowable.

The rejection (OA p. 3) of claim 1 over Sawyer US 5,156,613 under Sect. 102b is respectfully traversed. The collagen that is temporarily adhered in place with fibrin glue is not the final tissue repair material until it is melted, as is clear from Sawyer's description in the first half of the paragraph at col. 2 lines 23 – 32, in which the mention of the use of fibrin is made later in the paragraph (next sentence, lines 32 – 37) in a context that is clearly supplementary to the act of melting the collagen. In Sawyer, only collagen melting, and not fibrin gluing, will produce tissue repair. Since a key step of Sawyer is omitted, Sawyer does not anticipate applicant's claim.

Claim 3 appears to be dependent on claim 1 and to not raise any additional issues, and so is likewise believed to not be anticipated by Sawyer.

Claim 5 is directed to a situation in which the adhesive acts on multiple points of a preformed laterally-extended prosthetic, such as a mesh, as the sole adhesive. It is different from Sawyer in that the restorative act is achieved by the attachment of the prosthetic to the tissue by the fibrin, without requiring additional actions, in particular without melting of a collagen rod. Claim 5 is therefore not anticipated by Sawyer.

Claim 10 has a pre-formed prosthetic made of collagen. Again melting is not required, and Sawyer does not anticipate.

Claim 1 is rejected (OA p.4) under 103a over Polson et al US 5,487,897 alone. The rejection is respectfully traversed. Polson forms an "implant precursor" by dissolving a biodegradable polymer such as polylactide in a water-miscible solvent such as N-methyl

pyrrolidone. The polymer solution may be applied to tissue, either neat (col 3 line 30-32) or after pre-forming a sheet of polymer on a substrate (3/32-36; see also 3/8-29). Preforms may be adhered in place on the tissue if desired (3/46-54) with the polymer solution itself (col. 16/58 to 17/3) or with "a water-soluble substance such as gelatin" [which will later dissolve: col. 17/50-60 ] by applying the solution or the gelatin, and then applying an "implant precursor" to the site. The system has many alleged uses.

In applicant's Claim 1, a tissue defect is repaired by applying to an internal defect a prosthetic coated on at least one side with adhesive before application to tissue. This is not what Polson does, and there is no motivation provided in Polson to do it.

It is believed that Examiner asserts that it is "prima facie" ["on first appearance"] obvious to do this, or, in effect, that it is self-evident. However, because of the ease of finding obviousness in hindsight, it is well established that a rejection under 103 requires a specific reason, found in the reference itself, to look to the alternative technique with a reasonable expectation of success. No such reason is found in the reference, and hence Polson is not sufficient as a reference under 103. It is possible that Examiner may submit his reasoning as an affidavit. If so, he is invited to explain, using only Polson and without reference to applicant's application, what would induce a reader of Polson to do what applicants claim.

Claims 4, 6 and 8 are rejected under 103a over Sawyer in view of English et al (US 4,804,691). Claims 4, 6 and 8 are dependents of claim 1. In these dependent claims, the adhesive is described, respectively, as being based on cyanoacrylate, on polyurethane, and on polyisocyanate. English mentions a number of tissue adhesives in col 1 and col. 2, but finds them all lacking (col 2 lines 42-55), and proposes a particular type of biodegradable adhesive based on polylactide and similar polymers, end-capped with an isocyanate.

If claim 1 is allowable, as applicants believe, the rejection is moot. Moreover, there is no motivation in English to use the cited adhesives in the technique of Sawyer with a reasonable prospect of success; instead, English teaches away, and hence does not make it obvious to use the particular adhesives in applicant's invention. Even if the references could properly be combined without use of hindsight, the invention is not

taught, but only another way of temporarily positioning a collagen rod before melting it with a laser. The rejection is therefore respectfully traversed.

Claim 9, which is Claim 1 in which albumin solder is the adhesive, is rejected under 103a over Polson (US 5,487,897), cited above, in light of Owen et al (US 6,211,335), which describes a light-cured albumin tissue solder. As noted above, the rejection is moot if claim 1 is allowable. Moreover, there is not the slightest motivation to combine the references in either of them, and Examiner has failed to cite such a motivation.

Claim 7, which is Claim 1 in which the adhesive is a foamed polyurethane, is rejected under 103(a) over Polson or Sawyer in view of Ganster. The above arguments are repeated.

Claim 2, which is claim 1 wherein the adhesive is encapsulated, is rejected over Sawyer in view of Kreamer (US 4,577,631). Again, independent claim 1 is believed to be allowable, in which case the rejection of claim 2 is moot. Sawyer teaches melting collagen, optionally tacked in place by an adhesive, to repair a defect. Kreamer teaches coating a graft used to strengthen the aorta with an adherent material to seal the graft to the aorta, using the pressure of a balloon. The encapsulated adhesive of Kramer, which would rely on the force of the balloon, is not a likely substitute into Sawyer's technique, and in any event Sawyer still does the repair by melting collagen, and likewise is still inapplicable to applicant's invention. There is nothing in the references themselves to suggest to a skilled person to combine them. Were they combined, so that Sawyer used encapsulated adhesives to temporarily position his collagen rods prior to melting the rods with a laser, the combination would not teach applicant's invention. The rejection is respectfully traversed.

Claims 11 and 17 have been amended into independent form incorporating the limitations of claim 1, as suggested by Examiner, and are believed to be allowable.

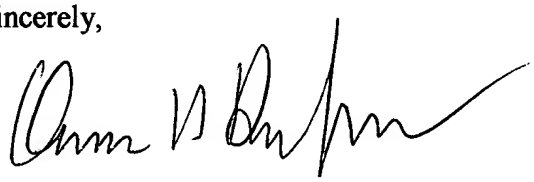
RELATED APPLICATIONS

A list of co-pending application that "set forth similar subject matter" is requested, along with copies of their claims. It is not clear what breadth "similar" is intended to cover. To comply, applicant has placed its 5 current published applications and 3 issued patents, all involving tissue adhesives and bulking agents, in the attached IDS. Copies are presented with the IDS. It is believed that this disclosure will serve the intent of the requirement.

Several pending Provisional applications are potentially relevant to the present case. However, there have been no pleadings involving the claims of these cases, and in addition placing their claims in the file history of the present application seems inappropriate. The appropriate procedure appears to be to cite the present case in regular applications based on related provisional cases, in due course. However, if Examiner wishes to examine the provisional cases, and it is appropriate to do so, applicants will willingly provide the application numbers, or the claims, on request.

It is believed that all of Examiner's objections and rejections have been addressed. Claims 11, 17 and 13 have been amended as suggested by examiner, and are believed to be allowable. It is believed that the rejections of Claim 1 under §102 and 103 has been traversed, in which case its remaining dependent claims should be allowable. If that should not be found to be the case, consideration is requested for allowing any of the dependent claims of claim 1 (other than any claims found to be allowable in independent form) to depend on claim 11, for example via Examiners amendment.

Sincerely,



Francis H Kirkpatrick
Reg. # 35,219
978-790-7186; fax 978-256-3679

collagen material. The prosthetic may be formed of a material selected from the group consisting of: polytetrafluorethylene or a fibrotic polypropylene stimulator material. The tissue defect may be an inguinal hernia. The method may include placing at least one absorbent pad on the tissue; delivering the adhesive onto the absorbent pad on the tissue; and suturing the adsorbent pad to the prosthetic. The invention includes a method for repairing a defect in living tissue comprising, attaching a syringe to a catheter; delivering a surgical adhesive through the catheter from the syringe to the tissue defect, and covering the tissue defect and surrounding tissue with the surgical adhesive, the surgical adhesive being mixed with a plurality of filaments of a second solid substance so that when the adhesive cures to the tissue the second solid provides a randomized matrix fully encapsulated by the adhesive. The filaments of the second solid may selected from the group comprised of polypropylene or e-PTFE measuring between 100 and 500 microns in length and between 25 and 100 microns in diameter, the filaments being mixed with the adhesive prior to application in a filament to adhesive volume ratio of about 1:10 to 1:2. The method may include mixing a portion of collagen spheres measuring between 100 and 500 microns in diameter with the adhesive prior to application onto the tissue, the spheres to adhesive mixed in a ratio of about 1:10 to 1:2. The